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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,510	06/07/2000	Pramod B. Mahajan	1121	9021

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,510

Applicant(s)

MAHAJAN, PRAMOD B.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3-9 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 16 is/are allowed.
- 6) ☐ Claim(s) 1,3-9, 14, 17, 18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) 15 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/18/02 has been entered. Amendment D has been entered.

1. Claims 1, 3-9 and 14-28 are pending and are under examination.

New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-9 and 14, 17-18, 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "a polynucleotide encoding a polypeptide having helicase activity". The phrase "polypeptide having helicase activity" has no basis in the specification or in the claims as originally filed. While the word "helicase" is recited in page 2 of the specification, a "polypeptide having helicase activity" is never mentioned, and therefore, is considered to be a New matter. Claim 21 recites a "non-human host

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cell". However, the word "non-human" has no basis in the specification or in the claims as originally filed. Applicant is required to delete the "non-human"; and to replace the "helicase" with ---RuvB---, since a "polypeptide having helicase activity" and "non-human" have no basis in the specification or in the claims as originally filed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-9 and 14, 17-18, 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claims 1 and 17, it is suggested that a " member" is changed to a --- nucleic acid sequence---. Dependent claim 3-9, 18, 20-26 are included in the rejection.

7. Claim 27 is indefinite for depending upon claim 45. In the interest of compact prosecution, the claim is considered to depend upon claim 23.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 3-9 and 14, 16-18 and 20-28 are rejected under 35 U.S.C. 112, **first paragraph**, because the specification, while being enabling for the isolated polynucleotide of SEQ ID NO: 3 or a polynucleotide encoding SEQ ID NO: 4 having RuvB activity and transgenic plant/plant/seed comprising said sequence, does not

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reasonably provide enablement for any isolated polynucleotide having at least 90% or 95% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having helicase activity or transgenic plant and plant cell or seeds or a polynucleotide encoding a polypeptide comprising at least 50 contiguous amino acids of SEQ ID NO:4 with no known function or a polynucleotide of 100 contiguous bases of SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

10. Applicant broadly claims an isolated polynucleotide sequence having at least 90% or 95% sequence identity with the disclosed sequence and encoding a polypeptide with helicase activity. However, Applicant has not provided sufficient guidance as how to obtain any and all polynucleotides having said structural identity and still encoding a polypeptide with the desired functional activity. No specific guidance has been provided for any modification to SEQ ID NO: 3 that resulted the polynucleotides of 1, 16-18 and 28. Applicant has not disclosed or provided guidance even a single polynucleotide having 90% or 95% sequence identity to the disclosed sequence and still encoding a polypeptide having helicase activity. Claims 16 and 28 are included in the rejection because specification is not enabling for a polynucleotide encoding any 50 contiguous amino acids of SEQ ID NO: 4 or a polynucleotide comprising any 100 contiguous bases of SEQ ID NO:3 that retains helicase activity. In addition, no single polynucleotide that encodes any 50 contiguous amino acids of SEQ ID NO: 4 or a polynucleotide

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comprising any 100 contiguous bases of SEQ ID NO:3 and that retains helicase activity has been shown.

11. While determination of sequence identity and assays of testing protein activity are well within the level of one skilled in the art, specific guidance are required to modify SEQ ID NO: 3 so that a polynucleotides having both the desired structural and functional characteristics can be obtained. The state of the prior art teaches that structural identity between two DNA/protein sequences does not necessarily mean that the sequences have the same function, even if the % of sequence identity is relatively high. For example, Lazar et al (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1257 (U)) teach a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (see at least the Title). Broun et al (Science, 13 November 1998, vol. 282, pp. 131-133 (U)) teach as few as four amino acid substitutions in a protein can change the protein activity (Abstract). Applicants note the nucleic acid sequences encoding the proteins disclosed by either Lazar or Broun would share at least 90% or 95% sequence identity to SEQ ID NO: 3. Therefore, sequence identity alone cannot be used to predictably determine the function of a protein/DNA.

12. Therefore, given the lack of guidance as discussed supra, the unpredictability; lack of working examples, the state of the art, one skilled would not be able to practice the invention as broadly claimed.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027 (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to

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practice until the inventor can define it by its "physical or chemical properties" (e.g. a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1, 3-9 and 14, 17-18 and 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated polynucleotide sequence having at least 90% or 95% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having helicase activity. Applicant has only described the isolated polynucleotide encoding SEQ ID NO: 4. These are genus claims. Claim 28 is included in the rejection because no function is recited in the claim for the encoded polypeptide. In addition, Applicant has not described a single polynucleotide encoding a polypeptide comprising any 40 contiguous amino acids of SEQ ID NO: 4 and that retains helicase activity. Since Applicant has not described a single species of a polynucleotide having 90% or 95% sequence identity to the disclosed sequences and encoding a polypeptide having helicase activity or the polynucleotide of claim 28, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed. See Written description Examination Guidelines published in Federal

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Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997).

Remarks

Claims 1, 3-9 and 14-28 are free of the prior art of record.

13. Claims 15 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

11/26/02
Mai


ELIZABETH F. McELWAIN
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